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| This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. |

**PATIENT GROUP DIRECTION (PGD)**

**Administration of TETRACAINE HYDROCHLORIDE 0.5% and 1% W/V EYE DROPS**

**For topical instillation into the conjunctival sac for use before minor ocular procedures, examination of the eye and to facilitate removal of a foreign body or thorough eye irrigation.**

Version Number 0.5

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| **Change History** |
| **Version and Date** | **Change details** |
| V0.5 | New PGD for PCNs based on Sirona and Bristol Eye Hospital PGDs |

Each organisation using this PGD must ensure that it is formally signed by a senior pharmacist, a senior doctor and any other professional group representatives involved in its review and that it is reviewed in line with the organisations’ PGD governance system. The organisation’s governance lead must sign to authorise the PGD on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorized by their organisation to practice under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

**PGD DEVELOPMENT GROUP**

|  |  |
| --- | --- |
| Date PGD template comes into effect:  | March 2025 |
| Review date | August 2028 |
| Expiry date:  | February 2028 |

This PGD template has been peer reviewed by the BNSSG PGD short life working group.

**This section MUST REMAIN when a PGD is adopted by an organisation.**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Breda Cronnolly | Lead Pharmacist Medicines Information, UHBW |
| Michelle Jones | Principal Medicines Optimisation Pharmacist, BNSSG ICB |
| Laura Barber | Sister/Ophthalmic Nurse Practitioner, UHBW |
| Matthew Pitman  | Senior Pharmacist – Medicines Governance, Sirona Care and Health |
| Kate Ellis | Head of Medicines Optimisation, Sirona Care and Health |

**The PGD template is not legally valid until it has had the relevant organisational approval - see below.**

**ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS**

The PGD is not legally valid until it has had the relevant organisational authorisations.

To ensure compliance with the law, organisations must add local authorisation details i.e. clinical authorisations and the person signing on behalf of the authorising organisation. You may either complete details below or delete and use a format agreed according to local PGD policy which complies with PGD legislation and [NICE MPG2 PGD 2017](https://www.nice.org.uk/Guidance/MPG2).

|  |  |  |  |
| --- | --- | --- | --- |
| **Name**  | **Job title and organisation**  | **Signature** | **Date** |
| **Senior doctor**  |  |  |  |
| **Senior pharmacist** |  |  |  |
| **Senior representative of professional group using the PGD**  |  |  |  |
| **Person signing on behalf of** [**authorising body**](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#authorising-body) |  |  |  |

It is the responsibility of the provider organisation to ensure that all legal and governance requirements for using the PGD are met.

To meet legal requirements, authorising organisations must add an Individual Practitioner Authorisation sheet or List of Authorised Practitioners. This varies according to local policy and how the service is managed but this should be a signature list or an individual agreement.

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

**ORGANISATIONS MAY ALSO ADD:**

* Local training and competency assessment documentation
* Other supporting local guidance or information
* Links to local PGD Policy and other supporting guidance
* Audit requirements

Any reference to a Trust protocol (either clinical to be followed as part of the administration of a medication with the PGD or for any other purpose) must be referenced and hyperlinked to ensure the practitioner acting under the PGD has direct access to the protocol for reference.

This PGD is for use by the services below:

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| Authorised for use by the following organisation and/or services |
| Suitably trained healthcare professionals working within a BNSSG organisation  |
| Limitations to authorisation |
| *E.g. Any local limitations the authorising organisation feels they need to apply in line with the way services are commissioned locally or limiting the professions within an organisation who may operate under the PGD. For example ‘This organisation does not authorise the use of this PGD by …’* |

|  |
| --- |
| Organisational approval (legal requirement) |
| Role | Name  | Sign | Date |
|  |  |  |  |

|  |
| --- |
|  Additional signatories according to locally agreed policy |
| Role | Name  | Sign | Date |
|   |   |   |   |
|   |   |   |   |
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Local enquiries regarding the use of this PGD may be directed to organization to insert contact details

1. **Characteristics of staff**

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| --- | --- |
|  **Qualifications and professional registration** | * Current contract of employment within a BNSSG provider organisation
* Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
 |
| **Initial training** | * Must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction (PGD) before working to it.
* Has undertaken appropriate training and been assessed as competent to carry out clinical assessment of individual leading to diagnosis that requires treatment according to the indications listed in this PGD
* Must have undertaken appropriate training for working under PGDs for supply/administration of medicines
* Must be competent in the use of PGDs (see [NICE Competency framework](https://www.nice.org.uk/guidance/mpg2/resources) for health professionals using patient group directions)
* Must be competent in the recognition and management of anaphylaxis
* Must have access to the PGD and associated online resource
* Should fulfil any additional requirements defined by local policy

***The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of individual leading to diagnosis of the conditions listed.*** |
| **Competency assessment** | *Staff operating under this PGD are encouraged to review their competency using the* [*NICE Competency Framework for health professionals using patient group directions*](https://www.nice.org.uk/guidance/mpg2/resources)***Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.*** |
| **Ongoing training and competency** | Practitioners should be aware of any change to the recommendations for the medicine listed.Practitioners must ensure they are up to date with relevant issues and clinical skills relating to joint injection therapy and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).Annual updates in anaphylaxis and cardiopulmonary resuscitation to reinforce and update knowledge and skills in this area of practice, including basic resuscitation and anaphylaxis training, with particular reference to changes and national directives. |
| ***The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies****.*  |

1. **Clinical condition or situation to which this PGD applies**

|  |  |
| --- | --- |
| **Clinical condition or situation to which this PGD applies** | * Ocular local anaesthetic for topical instillation into the conjunctival sac for use before minor ocular procedures, examination of the eye and to facilitate removal of a foreign body or thorough eye irrigation.
 |
| **Criteria for inclusion** | * Adults and children aged 28 days and over
* Valid informed consent
* Children under 16 should demonstrate Gillick competence , or consent for treatment must be given by an adult with parental responsibility
* Eye condition requiring local anaesthetic to carry out assessment/examination and treatments
 |
| **Criteria for exclusion** | * No valid consent
* Premature babies and neonates (less than 28 days old)
* Hypersensitivity to tetracaine hydrochloride or any component
	+ - * Concomitant use of sulfonamides.

**Primary care and community non-specialist clinic only – Refer to ophthalmology**Known penetrating globe injury. All injuries caused by sharp objects (such as glass, knives, thorns, darts, pencils) or high velocity injuries (such as from drilling, lawn mowing or hammering) should be treated as penetrating injuries until proved otherwise, as a foreign body may not be visible.* Significant orbital or peri-ocular trauma has occurred.
* Retained foreign body that cannot be removed safely in primary care.
	+ - * Recent eye surgery within last 6 weeks (e.g cataracts)
			* Suspected damage to retina
			* Marginal lacerations (as the lacrimal ducts may be damaged)
			* History of iritis
			* Photophobia with associated fever
			* Ophthalmic shingles
			* Infection or corneal ulcer is suspected.
* Eye condition not responding to previous prescribed treatments.
* Any of the following red flag clinical features are present:
	+ Severe pain.
	+ Irregular, dilated or non-reactive pupils.
	+ Significant reduction in visual acuity.
	+ Large or deep abrasions (>60% of the eye)
	+ Corneal opacity.
* The patient is unable to tolerate examination or foreign body removal in setting
* Pregnancy
* Breast-feeding
 |
| **Cautions including any relevant action to be taken** | * + - * May cause transient blurring of vision on instillation. Warn patients not to drive or operate hazardous machinery until vision is clear.

**Secondary care only*** + - * Pregnancy – use only when considered essential seek advice from prescriber.
			* Lactation – use only when considered essential seek advice from prescriber seek advice from prescriber.

**Primary and community care non-specialist clinic only*** + - * Young child who may be difficult to examine – have a low threshold for referral of young children who may not be able to explain symptoms or are reluctant to open their eye for examination.
			* Metallic foreign bodies may leave a rust ring which requires follow up and removal by ophthalmology within 1-2 days.
			* Ensure patients with chemical eye injury are followed up in the eye clinic.
			* Hyphaema (blood in the anterior chamber of the eye) – Please note this is a red flag and if found after examination then patients must be referred to the eye clinic.
			* Consider discussion with prescriber/referral to ophthalmologist if the person is suspected of having:
	+ The foreign body cannot be removed.
	+ Pain not relieved by topical local anaesthetic.
	+ Recurrent erosion syndrome
	+ A superficial corneal injury associated with contact lens use.
	+ An abrasion that is not improving or worsening 24 hours after initiation of treatment in primary care.
	+ A rust ring that remains after the removal of a metallic foreign body.
 |
| **Action to be taken if the patient is excluded** | * + - * Record reasons for exclusion and any action(s) taken in patient notes
			* Advise patient on alternative treatment
			* Refer to a prescriber/supervising doctor if appropriate
 |
| **Action to be taken if the patient or carer declines treatment** | * + - * Document advice given and the decision reached
			* Advise patient on alternative treatment
			* Refer to a prescriber/supervising doctor if appropriate
 |
| **Arrangements for referral for medical advice** | * If the patient presents with a recurrence of their symptoms, consider onward referral in line with trust/provider policy.
 |

1. **Description of treatment**

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| --- | --- |
| **Name, strength & formulation of drug** | Minims tetracaine hydrochloride 5mg/ml (0.5% w/v) and 10mg/ml (1% w/v) single use sterile eye drop solution  |
| **Legal category** | Prescription-only medicine (POM). |
| **Route / method of administration** | Ocular  |
| **Indicate any off-label use****(if relevant)** | Not applicable |
| **Dose and frequency of administration** | Instil ONE drop into the conjunctival sac repeated if necessary at 90 second intervals up to a maximum of three drops. Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children).In vitro studies have shown that tetracaine has a high affinity for melanin, therefore, differences in duration of action may be expected between deeply pigmented eyes and less pigmented eyes. 1% drops should be used for darker eyes and 0.5% for lighter coloured eyes.Each minims unit should be discarded after use.One minim can be used to treat both eyes if necessary, unless a purulent discharge, suggestive of infection, is evident. |
| **Duration of treatment** | Single treatment period |
| **Quantity to be supplied**  | Not applicable |
| **Storage** | Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) |
| **Drug interactions** | Tetracaine should not be used in patients being treated with sulphonamides**This list is not exhaustive*. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website:*** *www.medicines.org.uk*  |
| **Identification & management of adverse reactions** | * Initial burning sensation and blurring of vision which may last up to 30 seconds
* Prolonged use of anaesthetic drops may damage cornea.
* Dermatitis in hypersensitive patients
* Corneal disorders such as superficial punctuate keratitis or oedema may be observed following short-term application of Tetracaine (amethocaine) eye drops for topical anaesthesia.
* Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children).

A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: [***www.medicines.org.uk***](http://www.medicines.org.uk) |
| **Management of and reporting procedure for adverse reactions** | * + - * Access to adrenaline 1:1000 must be available for anaphylaxis management.
			* Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <https://yellowcard.mhra.gov.uk>
			* Record all adverse drug reactions (ADRs) in the patient’s medical record.
			* Report via organisation incident policy.
 |
| **Written information to be given to patient or carer** | * Offer marketing authorisation holder's patient information leaflet (PIL) provided with the product.
 |
| **Patient advice / follow up treatment** | * + - * Inform the individual/carer of possible side effects and their management.
			* The individual/carer should be advised to seek medical advice in the event of an adverse reaction.
* Patients should be advised not to drive or operate hazardous machinery until normal vision is restored
* Advise that the anaesthetised eye should be protected from dust and bacterial contamination.
	+ - * Advise patient that sensitivity should be normal again after about 1 hour. Advise patients not to drive until any protective eye cover is no longer needed.
			* Advise patient that 10-15 minutes after the numbing effect of the drops have worn off, the eye may feel uncomfortable until the abrasion heals.
			* It is best not to put contact lenses on until at least 24 hours after any treatment has finished.
			* Oral analgesics e.g. paracetamol or ibuprofen may relieve pain
			* Advise patients to seek medical review if persistent symptoms after 24 hours or in event of worsening symptoms.
* **Advice for people with superficial corneal injuries:**
	+ Wearing sunglasses or staying out of areas of bright light may help with symptoms of light sensitivity.
	+ Advise the person on suitable eye protection to prevent injury in the future and provide patient information.
	+ The eye should not be touched or rubbed and contact lenses should be avoided while the eye recovers.
	+ Patient information on [Eye injuries](https://www.nhs.uk/conditions/eye-injuries/) is available from NHS Choices at [www.nhs.uk](https://www.nhs.uk/conditions/).
 |
| **Records** | ***Record:*** * + - * that valid informed consent was given
			* name of individual, address, date of birth and GP with whom the individual is registered (if relevant)
			* name of registered health professional
			* Indication for use
			* name and brand of medication administered
			* date of administration
			* dose, form and route of supply/administration
			* quantity administered
			* batch number and expiry date (if applicable)
			* advice given, including advice given if excluded or declines treatment
			* Referral arrangements (including self-care)
			* Any additional advice sought from a doctor or other healthcare professional
			* details of any adverse drug reactions and actions taken
			* supplied via Patient Group Direction (PGD)

Records should be signed and dated (or a password-controlled e-records). All records should be clear, legible and contemporaneous.A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. |

1. **Key references**

|  |  |
| --- | --- |
| **Key references**  | * + - * Electronic Medicines Compendium <http://www.medicines.org.uk/>
			* Electronic BNF <https://bnf.nice.org.uk/>
			* NICE Medicines practice guideline “Patient Group Directions” <https://www.nice.org.uk/guidance/mpg2>
			* NICE Clinical Knowledge Summaries. Corneal Superficial Injury [Corneal superficial injury | Health topics A to Z | CKS | NICE](https://cks.nice.org.uk/topics/corneal-superficial-injury/)
 |

1. **Registered health professional authorisation sheet**

**PGD Name/Version: Tetracaine hydrochloride 1% eye drops v0.5**

**Valid from: Expiry:**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

**Registered health professional**

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

|  |
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| **I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.** |
| **Name** | **Designation** | **Signature** | **Date** |
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**Authorising manager**

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| **I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation for the above named health care professionals who have signed the PGD to work under it.** |
| **Name** | **Designation** | **Signature** | **Date** |
|   |   |   |   |

**Note to authorising manager**

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation. This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.